ARKANSAS STATE MEDICAL BOARD

REGULATION 27

INFORMED CONSENT FOR GASTRIC BYPASS SURGERY

Pursuant to Act 1356 of the 84th General Assembly of 2003, all physicians in this state, prior to performing gastric bypass surgery, also known as open or laproscopic Roux En Y, will have the patient sign an informed consent form acknowledging that they have been told information about and various complications that can result from the surgery. The complications and information the patient must be informed of are as follows:

- A. The potential risks, complications and benefits of the weight loss surgery.
- B. The alternatives to surgery including non-surgical options.
- C. The need for dietary changes, a development of an exercise plan and the possible need for counseling.
- D. The importance of proper nutrition, eating a balanced diet and taking vitamin and mineral supplements for the remainder of their life.
- E. There is no guarantee of weight loss and the need for long term weight management as a result of getting the surgery.
- F. A life time of follow-up medical care is required.
- G. Lab work will be required annually or more often than that as directed by the physician.
- H. Potentially serious complications from the surgery could result in death, further surgery, or prolonged hospital stays for the patient.
- I. The following surgical complications may arise:
 - (1) Bleeding, this may require a transfusion of blood or blood products

(2)	Surgical site infections, either superficial or deep to include port
	sites for laproscopic access. These could lead to wound
	breakdowns and hernia formation.
(3)	Perforations (leaks) of the stomach or intestine causing peritonitis,
	subphrenic abscess or enteroenteric or enterocutaneous fistulas.
(4)	sepsis
(5)	Systemic Inflammatory Response Syndrome (SIRS)
(6)	Adult Respiratory Distress Syndrome (ARDS)
(7)	Myocardial infarction (heart attack)
(8)	Cardiac rhythm disturbances
(9)	Congestive heart failure
(10)	Atelectasis
(11)	Pneumonia
(12)	Pulmonary edema (fluid in the lungs)
(13)	Pleural effusions (fluid around the lungs)
(14)	Injury to adjacent structures, including the spleen, liver,
	diaphragm, pancreas and colon.
(15)	Possible removal of the spleen
(16)	Stroke
(17)	Kidney failure
(18)	Pressure sores
(19)	deep vein thrombosis (blood clots in the legs or arms)

(20)	pulmonary embolism (clots migrating to the heart and lungs)			
(21)	staple line disruption			
(22)	Ulcer formation (marginal ulcer or in the distal stomach)			
(23)	Small bowel obstructions			
(24)	Internal hernias			
(25)	Incisional hernias, this includes port sites for laproscopic access			
(26)	Dehiscence or evisceration			
(27)	Inadequate or excessive weight loss			
(28)	Kidney stones			
(29)	Gout			
(30)	Encephalopathy			
(31)	Stoma Stenosis			
(32)	Urinary tract infections			
(33)	Esophageal, pouch, or small bowel motility disorders			
Nutritional Complications to include:				
(1)	Protein malnutrition			
(2)	Vitamin deficiencies, including B12, B1, B6, Folate and fat soluble			

- (3) Mineral deficiencies including calcium, magnesium, iron, zinc and copper
 - and other trace minerals.

vitamins A, D., E, and K

J.

(4) Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve damage

K.	Psychiatric	sychiatric complications to include:		
	(1)	Depression		
	(2)	Bulimia		
	(3)	Anorexia		
	(4)	Dysfunctional social problem		
L. Other Complications to include:				
	(1)	Adverse outcomes may be precipitated by smoking		
	(2)	Constipation		
	(3)	Diarrhea		
	(4)	bloating		
	(5)	cramping		
	(6)	development of gallstones		
	(7)	Intolerance of refined or simple sugars, dumping, with nausea, sweating		
		and weakness		
	(8)	low blood sugar, especially with improper eating habits		
	(9)	vomiting, the inability to eat certain foods, especially with improper eating		
		habits or poor dentition.		
	(10	0) loose skin		
	(11) intertriginous dermatitis due to loose skin		
	(12	2) malodorous gas, especially with improper food habits		
	(13	3) hair loss (alopecia)		
	(14	l) anemia		

- (15) bone disease
- (16) stretching of the pouch or the stoma
- (17) low blood pressure
- (18) cold intolerance
- (19) fatty liver disease or non alcoholic liver disease (NALF)
- (20) Progression of existing of preexisting NALF or cirrhosis
- (21) vitamin deficiencies may already exist before surgery
- (22) diminished alcohol tolerance
- M. Pregnancy complications should be explained as follows:
 - (1) Pregnancy should be deferred for 12-18 months after surgery, or until after the weight loss is stabilized
 - (2) Vitamin supplementation during the pregnancy should be continued
 - (3) Extra folic acid should be taken if the pregnancy is planned.
 - (4) Obese mothers have a children with a higher incidence of neural tube defects and congenital heart defects.
 - (5) Pregnancy should be discussed with the obstetrician.
 - (6) Special nutritional needs may be indicated or necessary.
 - (7) Secure forms of birth control should be used in the first year after surgery.
 - (8) Fertility improves with weight loss

Some or all of the complications listed in this regulation may exist in a patient whether the surgical procedure of gastric bypass is performed on the patient or not. This regulation is not meant to imply that in all cases gastric bypass surgery is the only cause of these complications.

A failure of a physician to inform a patient prior to gastric bypass surgery of the above

complications and obtaining the patient's signature on a form acknowledging the same will be a violation of the Medical Practices Act and may result in disciplinary proceedings before the Board pursuant to law.